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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,340	07/31/2000	Victor Pan	LIFE-009	5593

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EXAMINER
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CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/630,340

Applicant(s)

PAN ET AL.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is in response to Applicants' remarks filed on August 10, 2005. Claims 11-18 are pending. No amendments were made to the claims.

#### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 11, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shartle '660.

Shartle '660 discloses an automated meter useful in testing for the presence of a sufficient amount of sample on a test strip. The meter comprises a means for obtaining reflectance data via a LED illumination source 42a (visible light source) and a detector 42b. The light source illuminates the sample port 12. The detector measures reflected light. A signal is provided denoting the presence of the sample. This signal causes an actuator 48 to release bladder member 14 and move sample further down the test strip. See col. 6, line 54 – col. 7, line 33. In figure 4, the automatic meter is shown as it acts on a test strip 10.

Shartle fails to explicitly teach that the reflected light is detected prior to the test strip entering into the meter. However, Shartle teaches that when sample is introduced at the sample application area, a reduction in the reflected light to the detector occurs, thereby triggering the release of the bladder. Thus, the detector, which collects the reflected light data, detects reflected light prior to sample being present at the sample application zone and when sample is present. The detector would not sense a reduction in reflected light if the detector did not detect reflected light prior to sample being present. Further, it would have been obvious to one of ordinary skill in the art that the reflected light is also detected prior to the test strip being inserted into the meter. At col. 6, lines 54-62, Shartle discloses that the user turns the meter on, thereby energizing the strip detector and sample detector. The reference

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further states that the strip is inserted and the presence of the strip blocks the illumination by LED 40a of detector 40b. Thus, it would have been obvious that the reflected light changes once the strip is inserted into the meter and a change in the reflected light would denote that the data is being collected prior to the strip being inserted and after the strip is inserted.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Shartle '660.

3. Claims 13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shartle '660 in view of US Patent 5,674,699 to Saunders et al.

Shartle '660 is described in detail above. Further, the reference fails to teach the claimed wavelength to use in irradiating the test strip.

Saunders et al '699 teaches that chemicals/compounds specifically absorb light at certain wavelengths. Saunders et al '699 further teaches that the absorbances of many chemicals/compounds are known and that one of ordinary skill in the art can readily determine the wavelength at which a particular assay should be conducted to obtain maximum results. See col. 13, lines 1-29. Thus, it would have been obvious to one of ordinary skill in the art to use a wavelength suitable for reflecting light from the particular sample being deposited on the test strip in conducting the method of Shartle '660.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Shartle '660.

#### ***Response to Arguments***

3. Applicant's arguments filed August 10, 2005 have been fully considered but they are not persuasive. Applicants argue that the Invention Disclosure submitted as a part of the declaration under

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37 CFR 1.131 (dated October 12, 2004) shows the claimed invention sufficiently enough to antedate the Shartle reference. Specifically, Applicants argue that all the evidence must be considered by the Examiner – including the declaration, exhibits, record and notes. The Examiner does not dispute Applicants' statement here. However, the Examiner disagrees that the declaration is a sufficient showing in itself, to establish possession of the claimed invention. Applicants declaration fails to show the means for actuating fluid sample movement as recited in both independent claims 11 and 15. Applicants have attempted to argue that this limitation is inherent in the declaration since Applicants discuss the limitations in the instant specification. Applicants must remember that they are attempting to prove that the instantly claimed invention was in their possession prior to the filing date of the instant invention. If Applicants rely on the specification for a portion of the claimed invention, then Applicants have not proven that that portion (the actuating means) was in their possession prior to the filing date of the application. Applicants must show their entire invention in the declaration. The declaration lacks a showing of the actuating means because the actuating means is not a part of the drawings submitted with the declaration. The rejection is therefore, maintained.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

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date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**MONIQUE T. COLE**  
**PRIMARY EXAMINER**